

## **REMARKS**

### **Status of Claims:**

Claims 4-9 and 16-28 are pending. Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable re-consideration of this case is respectfully requested.

### **Rejections Under 35 U.S.C. § 112(2<sup>nd</sup>):**

Claims 23-25 were rejected as improperly depending upon Claim 28. The Applicants hereby amend Claims 23-25 to depend from Claim 26 as suggested by the Examiner.

### **Rejections Under 35 U.S.C. § 103(a):**

**A. Claims 4, 5, 7, 16, 18, 21, and 25-28 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of Felberbaum et al. (1997) or Olivennes et al. (1994), in view of Ziegler et al. (1998), and further in view of Hall et al. (1991).**

The Examiner alleges Felberbaum teaches that GnRH antagonists can be administered in an IVF program to avoid premature LH-surges. The Examiner alleges Albano teaches similarly to Felberbaum.

The Examiner acknowledges that the references do not specifically teach determining a luteal phase of a first menstrual cycle or determining a follicular phase of a second menstrual cycle wherein said second menstrual cycle immediately succeeds said first menstrual cycle, as recited in Claim 26. The Examiner further admits that the references do not specifically teach terminating administration of the LHRH antagonist prior to the onset of menses, as recited in Claim 26.

Felberbaum relates to a single menstrual cycle wherein an LHRH antagonist is administered only after the onset of menses. (*See* Figure 2). The COH protocol of Felberbaum is a "Lübeck-Protocol" involving only a single menstrual cycle. (*See* page 400). Felberbaum, therefore, cannot anticipate, or render obvious, the present invention which claims administration

of an LHRH antagonist during a first cycle to regulate the timing of a second cycle. The Examiner admits that “Olivennes et al. teaches a method for programming an infertility treatment cycle having the same steps as Felberbaum et al.” Thus, neither Felberbaum, nor Olivennes, relates to the multiple-cycle regulation as claimed by the present invention.

The Examiner alleges that Ziegler teaches the desirability of advanced timing of the onset of controlled ovarian hyperstimulation (COH). Independent Claim 26 relates to terminating a luteal phase of a first menstrual cycle by the administration of a peptide LHRH antagonist. Ziegler controls the timing of COH by administration of the steroid, oestradiol, during said first menstrual cycle. Oestradiol is neither a peptide, nor is it an LHRH antagonist. The Examiner argues that Ziegler teaches “the desirability of permitting the advanced timing of COH treatments by starting the administration of a composition during the luteal phase of one period.” (See page 7, lines 17-19; present emphasis). However, the present invention does not claim the “administration of a composition.” The present invention claims administration of an LHRH antagonist. Oestradiol does not anticipate, nor render obvious, an LHRH antagonist.

The Examiner alleges that Hall teaches the administration of an LHRH antagonist in mid-luteal phase results in luteolysis. However, the peptide LHRH antagonist of Hall is not related to the steroid, oestradiol, taught by Ziegler. A person of skill in the art would not expect that a result produced by a steroid would, necessarily be brought about by a peptide. Thus, the person of skill would have no motivation to research the steroid literature for suggestions as to the actions of peptides.

**B. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felberbaum et al. (of record) or Olivennes et al (of record), in view of (ii) Ziegler et al. (of record), and further in view of (iii) Hall et al. (of record), and further in view of Garfield et al (of record).**

The inapplicability of Felberbaum, Olivennes, Ziegler, and Hall was discussed above. The Examiner cites Garfield as teaching clomiphene as a non-steroidal anti-estrogen. However, the present invention relates to LHRH antagonists not to estrogens or to anti-estrogens.

Moreover, Garfield does not relate to the missing teaching, the administration of an LHRH antagonist during a first luteal phase to induce the timing of a second menstrual cycle.

**C. Claims 6, 8, 9, 17, 19, 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (of record) or Olivennes et al (of record), in view of (ii) Ziegler et al. (of record), and further in view of (iii) Hall et al. (of record), and further in view of (iv) Deghengi et al (of record) or Rabasseda et al (of record.).**

The inapplicability of Felberbaum, Olivennes, Ziegler, and Hall was discussed above. The Examiner cites Deghengi and Rabasseda are cited as teaching specific LHRH antagonists. However, neither Deghengi nor Rabasseda relate to the missing teaching, the administration of an LHRH antagonist during a first luteal phase to induce the timing of a second menstrual cycle.

In view of the above discussion, the Applicants respectfully request the Examiner withdraw the rejections under § 103 as moot.

**Judicially Created Doctrine of Obviousness Double Patenting.**

Claims 1 and 4-9, 16-21, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 of Engel et al., in view of Ziegler et al., Hall et al., Deghengi, Rabasseda, and Kent, as applied above.

The Applicants re-allege their prior arguments. However, in order to advance the prosecution of the present application, the Applicants respectfully request the Examiner hold the present rejections in abeyance until such time as allowable claims are identified. The double patenting rejection may subsequently be addressed by means of a terminal disclaimer.

**CONCLUSION**

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If the examiner identifies any points that he feels may be best resolved through a personal or telephone

interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Please charge any fees or credit any overpayments associated with the submission of this response to Deposit Account Number 03-3975.

Respectfully submitted,

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